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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,947	12/11/2003	Brian McGonigle	BB1535 US NA	2511

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,947	MCGONIGLE, BRIAN	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-12, 21-30 and SEQ ID NO: 4 in the reply filed on 11/20/2006 is acknowledged.

Claims 13-20 are cancelled. Claims 1-12 and 21-30 are pending and examined.

Priority

The specification on page 1 line 2 states that priority is claimed to U.S. provisional filed 13 December 2003; however, the provisional was filed 13 December 2002 as indicated on the Application Data Sheet. The specification should be amended to conform to the date indicated on the ADS.

Claim Objections

Claims 10 and 30 recite a multiple dependency, that should be recited in the alternative (e.g. any one of claims). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method comprising polynucleotides having at least 75% sequence identity to at least 200 nucleotides of SEQ ID NO: 4 that when transformed into a plant would reduce the ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant; and plants and seeds thereof.

Applicants describe SEQ ID NO: 4.

Applicants do not describe any polynucleotides having at least 75% sequence identity to at least 200 nucleotides of SEQ ID NO: 4 other than SEQ ID NO: 4 that when transformed into a plant would reduce the ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotides having at least 75% sequence identity to SEQ ID NO: 2 or a stem loop structure thereby. Applicants only describe SEQ ID NO: 4. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotide sequence having at least 75% sequence identity

to at least 200 unspecified nucleotides of SEQ ID NO: 4 in sense, antisense or stem-loop orientation or structure. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for a polynucleotide having at least 75% sequence identity to at least 200 nucleotides of SEQ ID NO: 4 that when transformed into a plant would reduce the ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant, it remains unclear what features identify a polynucleotide having at least 75% sequence identity to at least 20 nucleotides of SEQ ID NO: 4 that would have said activity. Since the genus of polynucleotides has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that are 75% identical to SEQ ID NO: 4 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 4, as well as sequences having no known activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 1-12 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to to a method comprising polynucleotides having at least 75% sequence identity to at least 200 nucleotides of SEQ ID NO: 4 that when transformed into a plant would reduce the ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant; and plants and seeds thereof.

Applicants teach soybean transformed with an unspecified portion of SEQ ID NO: 4.

Applicants do not teach transformed plants that have a reduced ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant.

The state-of-the-art is such that one of skill in the art cannot predict the range of reduction of liquiritigenin-derived isoflavones when there is no control for comparison and the prior art teaches that the range of liquiritigenin-derived isoflavones can vary dramatically from cultivar to cultivar 1116 to 2743 microgram per gram (Wang *et al.* AOCS Press, 2000 Vol. 77 No. 5, pp. 483-487; see page 484 column 2 second full paragraph). Further, the Jack variety of Soybean of the instant Application was not included in the Wang study that Applicant recites in the comparison on page 3 of the specification. Furthermore, The values of the Wang study are

statistically averaged, while the values Applicant presents in table 4 are not. Moreover, Table 1 of Wang shows levels of genistein, daidzein, and glycitein that represent a summation of all free and conjugated forms, while those Applicant presents are measured levels of genistin, daidzin and glycitin not genistein, daidzein, and glycitein. It is entirely unclear what kind of comparisons Applicant is trying to make given that the range of results presented on average do not fall outside the range of what appears to be the normal range of liquiritigenin-derived isoflavone levels.

The unpredictability for hairpin vector design is shown in the effect of spacer sequences on silencing efficiency of plant RNAi vectors, whereby the strength of the silencing construct could only be determined by trial and error experimentation that would determine its usefulness in achieving an acceptable end product; and thus reducing the ratio of liquiritigenin-derived isoflavones would require undue trial and error experimentation (Plant Cell Reports EPUB 2007 Jan. 5; pp. 1-9; see last full paragraph pages 7 to 8).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to make a multitude of transformed plants with a myriad of constructs comprising unspecified portions of SEQ ID NO: 4 in sense antisense or stem-loop orientation or structure to determine which portions of SEQ ID NO: 4 or which sequences having at least 75% sequence identity to at least 200 unspecified nucleotides of SEQ ID NO: 4 would reduce the ratio of liquiritigenin-derived isoflavone levels in a transformed plant when compared to a comparable control plant.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claim 30 is drawn to seeds of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three fourths of the progeny (i.e. seeds) having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature.

All claims are rejected

Claims 1-12 and 21-30 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method for decreasing the ratio of liquiritigenin-derived isoflavone levels in a plant transformed with SEQ ID NO: 4; and transformed plants and transformed seeds thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
February 2, 2007

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER